UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte DAVID F. WOODWARD, STEVEN W. ANDREWS, ROBERT M. BURK and MICHAEL E. GARST

Appeal No. 2005-2534
Application No. 08/876,937

ON BRIEF

Before ELLIS, TORCZON, and GRIMES, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This appeal involves claims to treating glaucoma with certain prostaglandin derivatives. The examiner has rejected the claims over the prior art. We have jurisdiction under 35 U.S.C. § 134. We affirm the examiner's rejection and enter a new ground of rejection of claims 47 and 48.

Background

"Ocular hypotensive agents are useful in the treatment of a number of various ocular hypertensive conditions, such as . . . glaucoma, and as presurgical adjuncts." Specification, page 2. "[E]vidence accumulated in the last two decades shows that

some prostaglandins are highly effective ocular hypotensive agents and are ideally suited for the long-term medical management of glaucoma." Page 3.

"[O]cular surface (conjunctival) hyperemia and foreign-body sensation have been consistently associated with the topical ocular use of [prostaglandins], in particular PGF_{2a} and its prodrugs, e.g., its 1-isopropyl ester, in humans. The clinical potential of prostaglandins in the management of conditions associated with increased ocular pressure, e.g., glaucoma, is greatly limited by these side effects." Pages 3-4. The specification discloses that "certain cyclopentane heptanoic acid, 2-cycloalkyl or arylalkyl compounds and derivatives thereof wherein the carboxylic acid group is replaced by a non-acidic substituent . . . are potent ocular hypotensive agents." Page 4. These compounds are also said to "cause no or significantly lower ocular surface hyperemia [compared to] the parent compounds." Id.

The specification states that "[t]he present invention provides cyclopentane heptanoic acid, 2-cycloalkyl or arylalkyl compounds, which may be substituted in the 1-position with amino, amido, ether or ester groups, e.g., a 1-OH cyclopentane heptanoic acid, 2-(cycloalkyl or arylalkyl) compound." Page 1.

Discussion

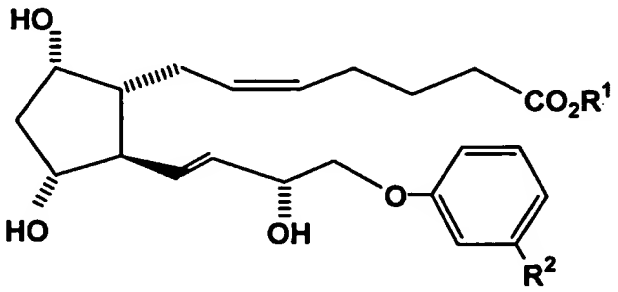
1. Claim construction

Claims 26, 27, 29-35, and 37-48[1] are pending. Claims 46-48 have been allowed (subject to an interference) and claims 26, 27, 29-35, and 37-45 stand rejected.

[1] Claims 2-25 were cancelled in a preliminary amendment received June 16, 1997; claim 1 was cancelled in a preliminary amendment received February 13, 1998; and claims 28 and 36 were cancelled in the amendment received November 4, 2002.

The rejected claims stand or fall together, because Appellants have not argued them separately. We will focus on claim 26, which reads as follows:

26. A method of treating glaucoma and ocular hypertension which comprises topically administering to the affected eye a therapeutically effective amount of a compound of formula:



wherein R^1 = hydrogen, a cationic salt moiety, [or] a lower alkyl; and R^2 = Cl or CF_3.

Thus, claim 26 is directed to a method of treating a patient having glaucoma or ocular hypertension, by administering a compound having the given chemical formula to the affected eye, in an amount that is therapeutically effective.

2. Anticipation

The examiner rejected claims 26, 27, 29-35, and 37-45 under 35 U.S.C. § 102(e) as anticipated by Bishop.[2] Bishop teaches "the use of cloprostenol, fluprostenol, and their pharmaceutically acceptable salts and esters for the treatment of glaucoma and ocular hypertension." Column 1, lines 10-12. Cloprostenol and fluprostenol are compounds within the formula recited in instant claim 26. Specifically, cloprostenol is the compound shown when R^1 is hydrogen and R^2 is Cl;[3] fluprostenol is the compound shown when R^1 is hydrogen and R^2 is CF_3. See Bishop, column 1, lines

[2] Bishop et al., U.S. Patent 5,510,383, issued April 23, 1996 (application filed August 3, 1993).
[3] In some places in the record, cloprostenol is referred to as "16-m-chlorophenoxy $PGF_{2\alpha}$" or "cyclopentane heptenoic acid, 5-cis-2-(3-α-hydroxy-4-m-chlorophenoxy-1-trans-butenyl)-3,5-dihydroxy [1_α, 2_β ,3_α, 5_α]."

25-45. Bishop teaches administration to the affected eye and preferred dosages (col. 4, lines 9-18). Thus, Bishop teaches the method defined by instant claim 26.

Appellants do not dispute that Bishop teaches the instantly claimed method and note that "claims 26-45 [sic] of this application have been copied from U.S. Patent 5,510,383, i.e., Bishop et al[.], to provoke an interference." Appeal Brief, page 3. Appellants argue, however, that Bishop is not prior art with respect to the instant claims because "pending claims 26 through 45 [sic] are supported in U.S. Patent Application 07/948,056, the Grandparent of the present Application having a filing date of September 21, 1992." Id., page 4.

According to Appellants, this application is a continuation of application serial number 08/605,567 (filed February 22, 1996), which was a continuation-in-part of application serial number 08/371,339 (filed January 11, 1995). The '339 application in turn claims priority to application serial number 07/948,056, filed September 21, 1992, now U.S. Patent 5,352,708. Specification, page 1. Appellants argue that the '056 application disclosed lowering intraocular pressure using cloprostenol, referred to in the '056 application as "16-m-chlorophenoxy $PGF_{2\alpha}$." See the Appeal Brief, page 4 (citing Table V of the '056 application). Appellants also point to Example 8 of the '056 application as disclosing the methyl ester of cloprostenol. See id.

With regard to fluprostenol, Appellants argue that they have submitted a declaration under 37 CFR § 1.131 that shows that they had "reduced to practice the present invention as related to fluprostenol," before Bishop's filing date. Appeal Brief, page 5. Thus, Appellants conclude that with respect to cloprostenol and fluprostenol,

they have "either an earlier filing date or declaration showing a reduction to practice prior to the filing date of Bishop." Id.

If the instant claims were accorded the benefit of priority under 35 U.S.C. § 120, based on the '056 application, then Appellants would be correct: Bishop would not be prior art with respect to them. However, "[i]t is elementary patent law that a patent application is entitled to the benefit of the filing date of an earlier filed application only if the disclosure of the earlier application provides support for the claims of the later application, as required by 35 U.S.C. § 112." In re Chu, 66 F.3d 292, 297, 36 USPQ2d 1089, 1093 (Fed. Cir. 1995). "[A] claim complies with 35 U.S.C. § 120 and acquires an earlier filing date if, and only if, it could have been added to an earlier application without introducing new matter." Studiengesellschaft Kohle m.b.H. v. Shell Oil Co., 112 F.3d 1561, 1564, 42 USPQ2d 1674, 1677 (Fed. Cir. 1997).

Here, if the rejection based on Bishop is to be overcome, the instant claims must be entitled to claim the benefit of the '056 application's filing date (September 21, 1992). At best, however, that application disclosed the claimed method only as practiced with cloprostenol and its methyl ester,[4] while the instant claim encompasses a method of using cloprostenol, fluprostenol and lower alkyl esters of both. Appellants have pointed to no disclosure in the '056 application that describes a method of using fluprostenol, esters of fluprostenol, or alkyl esters of cloprostenol other than the methyl ester. Nor have Appellants adequately explained how the limited disclosure of the '056 application would have shown possession of the broader, claimed process to those of ordinary skill

[4] In fact, while the application disclosed the methyl ester of cloprostenol, it did not teach using that compound to treat intraocular hypertension or glaucoma.

in the art. We therefore conclude that the '056 application does not meet the written description requirement of 35 U.S.C. § 112, first paragraph, with respect to the instantly claimed process.

Appellants' Rule 131 declaration cannot be relied on to make up for the deficiencies of the '056 application, even assuming that the declaration shows reduction to practice of a method of using fluprostenol to reduce intraocular pressure. In order to be entitled to the benefit of priority under § 120, the later-claimed invention must be disclosed in the earlier-filed application sufficiently to satisfy the requirements of § 112, first paragraph. A Rule 131 declaration cannot provide the disclosure missing from the earlier-filed application: "[P]roof of a reduction to practice, absent an adequate description in the specification of what is reduced to practice, does not serve to describe or identify the invention for purposes of § 112, ¶ 1." Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 969, 63 USPQ2d 1609, 1613 (Fed. Cir. 2002).

In addition, as discussed below, a Rule 131 declaration cannot be used to antedate a reference that both discloses and claims the same subject matter. Here, Bishop's claim 1 is directed to the same subject matter as instant claim 26 and therefore, the Rule 131 declaration cannot be relied upon to antedate the reference.

Claim 26 is not entitled to claim the benefit of priority under 35 U.S.C. § 120 based on the '056 application, because that application does not describe the method of claim 26 adequately to comply with 35 U.S.C. § 112, first paragraph. Therefore, Bishop is prior art under 35 U.S.C. § 102(e) with respect to claim 26. The rejection of claim 26 under § 102(e) is affirmed. Claims 27, 29-35, and 37-45 fall with claim 26. We need not address the alternative ground of rejection.

New Ground of Rejection

Under the provisions of 37 CFR § 41.50(b), we enter the following new ground of rejection: Claims 47 and 48 are rejected under 35 U.S.C. § 102(e) as anticipated by Bishop (U.S. Patent 5,510,383).

Claims 47 and 48 read as follows:

47. A method of treating glaucoma and ocular hypertension which comprises topically administering to the affected eye a therapeutically effective amount of fluprostenol.

48. A topical ophthalmic composition for the treatment of glaucoma and ocular hypertension in humans, comprising a therapeutically effective amount of fluprostenol.

As discussed above, Bishop teaches a method of treating glaucoma and ocular hypertension by topically administering fluprostenol. See col. 1, lines 10-12, and col. 4, lines 9-18. Bishop also teaches topical compositions comprising fluprostenol. See col. 4, line 19 to col. 5, line 2. Bishop therefore anticipates claims 47 and 48. In addition, Bishop claims methods of treating glaucoma and ocular hypertension with fluprostenol (see claims 1 and 5) and topical compositions comprising fluprostenol (see claims 9 and 13).

Appellants have argued that they have submitted a declaration under 37 CFR § 1.131 showing that they reduced to practice the method and composition of claims 47 and 48 before Bishop's filing date. See Appellants' response received November 27, 2000, pages 6-7.

A Rule 131 declaration, however, cannot be relied on to overcome a reference that claims the same subject matter. See MPEP § 715.05 ("When the reference in question is a noncommonly owned U.S. patent or patent application publication claiming

the same invention as applicant and its publication date is less than 1 year prior to the presentation of claims to that invention in the application being examined, applicant's remedy, if any, must be by way of 37 CFR 1.608 instead of 37 CFR 1.131."). See also MPEP § 2308.

Appellants have stated that "[f]luprostenol is . . . included in claim 1 of Bishop et al., when R^1 is hydrogen and R^2 is CF_3." Amendment received November 27, 2000, pages 6-7. We agree with Appellants' interpretation. Bishop's claims 5 and 13 are generic to fluprostenol, in that Bishop's R^1 group is not limited to hydrogen. However, Bishop states that fluprostenol was a known compound (column 1, line 13) having a hydrogen atom at R^1. Thus, fluprostenol would have been an obvious species within the scope of Bishop's generic claims. Appellants' claims are therefore directed to the "same invention" as the claims of the Bishop patent, and Appellants cannot rely on a Rule 131 declaration to antedate the reference.

Instead, Appellants must make the showing required by 37 CFR § 41.202 in order to provoke an interference with the Bishop patent.[5] Rule 202 reads as follows:

> § 41.202 Suggesting an interference
>
> (a) Applicant. An applicant, including a reissue applicant, may suggest an interference with another application or a patent. The suggestion must:
>
> (1) Provide sufficient information to identify the application or patent with which the applicant seeks an interference,
>
> (2) Identify all claims the applicant believes interfere, propose one or more counts, and show how the claims correspond to one or more counts,
>
> (3) For each count, provide a claim chart comparing at least one claim of each party corresponding to the count and show why the claims interfere within the meaning of § 41.203(a),

[5] 37 CFR § 1.608 was replaced by 37 CFR § 41.202, effective September 2004. The new rule will control future proceedings in this case.

(4) Explain in detail why the applicant will prevail on priority,

(5) If a claim has been added or amended to provoke an interference, provide a claim chart showing the written description for each claim in the applicant's specification, and

(6) For each constructive reduction to practice for which the applicant wishes to be accorded benefit, provide a chart showing where the disclosure provides a constructive reduction to practice within the scope of the interfering subject matter.

. . .

(d) Requirement to show priority under 35 U.S.C. § 102(g). (1) When an applicant has an earliest constructive reduction to practice that is later than the apparent earliest constructive reduction to practice for a patent or published application claiming interfering subject matter, the applicant must show why it would prevail on priority.

(2) If an applicant fails to show priority under paragraph (d)(1) of this section, an administrative patent judge may nevertheless declare an interference to place the applicant under an order to show cause why judgment should not be entered against the applicant on priority. New evidence in support of priority will not be admitted except on a showing of good cause. The Board may authorize the filing of motions to redefine the interfering subject matter or to change the benefit accorded to the parties.

(e) Sufficiency of showing. (1) A showing of priority under this section is not sufficient unless it would, if unrebutted, support a determination of priority in favor of the party making the showing.

As discussed above in relation to the examiner's rejection, the earliest-filed application to which Appellants claim priority under 35 U.S.C. § 120 fails to describe a method of using fluprostenol or a composition comprising fluprostenol. Therefore, claims 47 and 48 are not entitled to claim the benefit of the '056 application under § 120. The effective filing date of claims 47 and 48 appears to be February 22, 1996, the filing date of application 08/605,567, of which the present application is said to be a continuation.

Bishop has an effective filing date of August 3, 1993. Therefore, since the present application "has an earliest constructive reduction to practice that is later than the apparent earliest constructive reduction to practice for a patent . . . claiming interfering subject matter, the applicant must show why it would prevail on priority." 37 CFR § 41.202(d)(1). "A showing of priority under this section is not sufficient unless it would, if unrebutted, support a determination of priority in favor of the party making the showing." 37 CFR § 41.202(e).

Summary

The instant claims are not entitled to the benefit of priority under 35 U.S.C. § 120 based on application serial number 07/948,056. Therefore, Bishop is prior art with respect to the instant claims and the rejection under 35 U.S.C. § 102(e) is affirmed. In addition, Bishop cannot be antedated by way of a 37 CFR § 1.131 declaration. Therefore, Bishop is also prior art with respect to claims 47 and 48; those claims are anticipated as well.

Time Period for Response

Regarding the affirmed rejection(s), 37 CFR § 41.52(a)(1) provides "[a]ppellant may file a single request for rehearing within two months from the date of the original decision of the Board."

In addition to affirming the examiner's rejection(s) of one or more claims, this decision contains a new ground of rejection pursuant to 37 CFR § 41.50(b) (effective September 13, 2004, 69 Fed. Reg. 49960 (August 12, 2004), 1286 Off. Gaz. Pat. Office 21 (September 7, 2004)). 37 CFR § 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review."

37 CFR § 41.50(b) also provides that the appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

> (1) *Reopen prosecution.* Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the proceeding will be remanded to the examiner. . . .
>
> (2) *Request rehearing.* Request that the proceeding be reheard under § 41.52 by the Board upon the same record. . . .

Should the appellant elect to prosecute further before the examiner pursuant to 37 CFR § 41.50(b)(1), in order to preserve the right to seek review under 35 U.S.C. §§ 141 or 145 with respect to the affirmed rejection, the effective date of the affirmance is deferred until conclusion of the prosecution before the examiner unless, as a mere incident to the limited prosecution, the affirmed rejection is overcome.

If the appellant elects prosecution before the examiner and this does not result in allowance of the application, abandonment or a second appeal, this case should be returned to the Board of Patent Appeals and Interferences for final action on the affirmed rejection, including any timely request for rehearing thereof.

AFFIRMED, 37 CFR § 41.50(b)

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